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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/516,061	03/01/2000	Venkat Gopalan	50093/016001	3858

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EXAMINER

PATTERSON, CHARLES L JR

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 04/04/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/516,061	Applicant(s) GOPALAN ET AL.	
	Examiner Charles L. Patterson, Jr.	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002 and 14 January 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,8-11 and 13-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8-11 and 13-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>59</u> | 6) <input type="checkbox"/> Other: _____ |

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Applicant is reminded that, as outlined in the attachment to the PTO-948 sent with the action of 4/11/02, drawing changes may no longer be held in abeyance and must be submitted with the next action. In addition to the things noted in the instant review by the draftsman, the examiner hereby objects to the presence of the broad black lines in the instant figure, which obliterates the residues under it. The residues highlighted in gray can be seen but those highlighted in black cannot be seen.

The reply filed 10/17/02 is not fully responsive to the Office communication mailed 4/11/02 because the sequences in Figure 1 are still not labeled as to SEQ ID NO. The amendment to page 8, lines 22-27 states "the alignment of the RNase P sequences of the for the present invention (SEQ ID NO:39-95)". That is 57 sequences and only 53 sequences are included in Figure 1. Also, the sequences in Figure 1 are not labeled as to exactly which SEQ ID NO they correspond to. Again, because the application could be examined without these sequence disclosures this has been done, however this discrepancy must be corrected.

Claims 1, 2, 16 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ Claim 1 is incorrect in the recitation of the bacterial genera and specifies. These genera and species should be italicized.

✓ Claim 1 is apparently incorrect in the recitation of "J000513" on line 21. According to the Healy declaration this recitation should be "AJ000513".

7 Also, several of the organisms listed in claim 1 and the declaration do not have accession numbers. This is indefinite as there can apparently be more

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that one RNase P polypeptide in a given organism--witness "Escherichia coli (unspecified) M11056, Escherichia coli (K-12) AE000394", "Helicobacter pylori (22695) AE000645, Helicobacter pylori (J99) AE001557", "Chlamydophila pneumoniae (CWL 029) AE001673, Chlamydophila pneumoniae (AR39) AE002251" and "B. burgdorferi, B. burgdorferi-partial".

Claims 2, 16 and 20 are confusing in that they recite sequences that were not elected for prosecution. Applicant urges that they not be limited to the elected species at this time because if generic claims are not allowed they will restrict the claims to the species elected. This statement is noted but the instant rejection is maintained until such time as generic claims are allowed or these claims are so limited.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to polypeptides that, "when combined with an RNA subunit to form an RNase P holoenzyme, has at least 20% of the enzymatic activity of an *E. coli* or *B. subtilis* RNase P holoenzyme". The instant specification does not teach how much the activity is of the *E. coli* or *B. subtilis* RNase P holoenzyme nor what the activity of the claimed polypeptides are. Therefore, one of ordinary skill in the art would not know how much activity the claimed polypeptides are to have nor what the activity of *E.*

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coli or *B. subtilis* RNase P holoenzyme are that are to be compared with it. This ordinary artisan would not know the metes and bounds of the instant claims.

Claims 1, 2, 8-11 and 13-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:27, does not reasonably provide enablement for claims of the breadth of the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The instant specification teaches the sequences of 19 different RNase P proteins, SEQ ID NO:20-38. In response to the restriction requirement, applicants elected to prosecute SEQ ID NO:27. Applicants, after the instant amendment, are now claiming an RNase P "consensus sequence" that is not any of the RNase P molecules disclosed in a database on the internet as of March 3, 2002, the filing date of this application. Applicants have provided a declaration with this amendment listing all of the RNase P protein sequences present in the database as of this date and have eliminated the eukaryotic examples by limiting claim 1 to bacterial polypeptides. This declaration is taken as probative evidence of the sequences available on 3/1/00. However, the specification does not teach any and all polypeptide sequences that are not listed in the database but only 19 different ones, and applicants have elected to prosecute only one of these. The specification does not teach one of ordinary skill in the art how to make all of the sequences encompassed by the instant claims and that person would therefore not know how to make the claimed invention within the limits of the instant claims.

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Furthermore, there is no teaching that claims of the breadth of claims 9, 15 and 19 would have utility. The instant claims are drawn to polypeptides of claim 1 having 95% or 100% identity with 20 amino acids of *E. coli* RNase P. Applicants have not shown that these polypeptides have RNase P activity nor have they taught how to make any and all of these polypeptides.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(a or b) as being anticipated by either of Gress, et al. (AA), Guth, et al. (AB), Altman, et al. (AC & AD), Frank, et al. (AE), Gopalan, et al. (AF), Pace, et al. (AJ), Pascual, et al. (AK) or Peck-Miller, et al. (AG). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. Applicants argue that because the particular genus and species are now listed in claim 1 as not being

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including the polypeptide of the claim, the instant claims no longer read on these references. As noted *supra*, apparently some of these species have more than one RNase P polypeptide and applicants have not shown that the RNase P in the database is that of the instant claim.

Claims 8, 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Potuschak, et al. (U), Mikkelsen, et al. (V) or Schroeder, et al. (W). This rejection is repeated for the reasons given in the last action. Applicants arguments have been carefully considered but do not overcome the instant rejection. Applicants argue that "[n]one of these references...disclose or suggest the RNase P polypeptides recited in the present claims". Applicants did not further explain this statement but it is presumed that the argument is made because all of the claims depend upon claim 1, that the references do not read on the RNase P enzyme of that claim because of the language now excepting several RNase P molecules and therefore the instant claims would not have been obvious. For the reasons discussed *supra*, this argument is rejected. Furthermore, applicants have not even pointed out which RNase P enzyme is taught by the instant references.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final

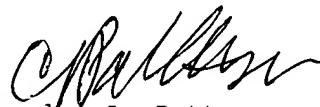
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action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone number is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
April 1, 2003